Abstract

EU Competition Law and Practices Hindering Market Entry of Drugs

This thesis deals with the legality of pharmaceutical companies' practices that hinder market entry of drugs, whether within the *intra-brand* or *inter-brand competition*, from the EU competition law perspective.

The aim of this thesis is to introduce the reader to the issue of different practices aimed at limiting parallel trade and also at delaying or complete prevention of the market entry of a new competing drug, and also to assess whether the competition authorities have established clear guidance on the performance of these practices, i.e. whether they are clearly set boundaries between acceptable restriction of competition which can be justified and distortion which cannot be allowed.

For the purpose of this assessment, the relevant decisions of the European Commission and the CJEU are analyzed, identifying the key factors on which the competition authorities place emphasis when assessing the compliance of such practices with the EU competition law, and general conclusions are drawn from these key factors to determine whether there is a sufficient degree of legal certainty for pharmaceutical companies engaging in these practices.

The thesis is divided into six chapters, of which chapters three, four and five form the main part. The necessary introduction is followed by a chapter that aims to introduce the reader to the basic aspects of the pharmaceutical market, its key players and the competitive relationships between them. It also provides a brief explanation of the process of obtaining a marketing authorization for drugs and of intellectual property rights, whose role in this sector is crucial and whose exploitation / abuse is often part of the examined practices.

The third chapter focuses on practices restricting parallel trade. In the beginning, parallel trade and its role in the EU are generally defined. Subsequently, the key decisions of the European Commission and the CJEU concerning supply quota and dual pricing systems are analyzed.

The fourth chapter introduces selected patent and other strategies that have been identified in the pharmaceutical sector inquiry as one of the causes of a decrease in the number of marketed drugs. Given the nature of this type of practice, which is in most cases unilateral, it

is analyzed in the light of Article 102 TFEU and special attention is paid to decisions in *AstraZeneca* and *Servier* cases.

The fifth chapter deals with patent settlement agreements, which, according to the European Commission, are one of the most problematic patent strategies used by pharmaceutical companies. This chapter discusses *Lundbeck* case where the General Court ruled on the patent settlement agreements and their compliance with the EU competition law for the first time.

In conclusion, there is a summary of the individual chapters' findings and the assessment that the European Commission and the CJEU have so far failed to provide clear guidance for such practices so that they are not in breach of competition rules and pharmaceutical companies continue to face great legal uncertainty in this respect.